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| 10/534,176 | 05/05/2005 | Reinhard Maletz | HOL2-11874 | 9987 |

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| EXAMINER | |
|---|---|
| PEPITONE, MICHAEL F | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/534,176 | MALETZ ET AL. | |
| | Examiner | Art Unit | |
| | MICHAEL PEPITONE | 1796 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7 and 9-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 November 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

The drawings were received on 11/23/09. These drawings are acceptable.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones *et al.* (US 2002/0193463); or Jones *et al.* (US 2002/0193463) in view of Heindl *et al.* (US 5,852,096).

Regarding claims 1, 11, and 17: Jones *et al.* teaches a filler for dental composite materials (¶ 1-2, 9-10) comprising a polymerizable organic binder and a filler in a quantity of 5-

35 weight% (¶ 65-68), wherein the filler particles are obtained by spray drying and have the shape of a doughnut {torus} with an average external diameter of 0.2 μm to 20 μm {with a mean size of 5 μm} [instant claims 1, 11, and 17] (¶29, 58); the filler particles undergo a heat treatment process at a temperature of about 600 °C {for about 24 h}, which completes the formation of holes within the discs and allows the smooth ovoid or round doughnut shaped particles to provide a lower residual stress within the matrix resin following polymerization (¶ 59). Jones *et al.* teaches the doughnut {torus} shaped filler particles are silanized (¶ 64).

Jones *et al.* does not teach post-curing the particles at a temperature of 800 – 1200 °C. However, the Office takes Official Notice that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) [MPEP 2144.05]. At the time of invention a person of ordinary skill in the art would have found it obvious to have optimized the furnace temperature, as taught by Jones *et al.*, as commonly practiced in the art, and would have been motivated to do so since the conversion of silica gel into silica glass, as well as the formation of holes in the discs of the composition is influenced by the temperature of the furnace.

Alternatively, Jones *et al.* does not teach post-curing the particles at a temperature of 800 – 1000 °C. However, Heindl *et al.* teaches silicon dioxide based filler for dental materials (1:5-10) wherein the filler is fired at 500 to 1000 °C after drying in order to reduce the percentage of silanol groups on the surface (3:5-15). Jones *et al.* and Heindl *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of silicon dioxide based filler for dental materials. At the time of invention a person of ordinary skill in the art

would have found it obvious to have combined firing at a temperature of 500 to 1000 °C after drying, as taught by Heindl *et al.* in the invention of Jones *et al.*, and would have been motivated to do so since Heindl *et al.* suggests that the firing provides a reduced percentage of silanol groups on the surface of the filler, yielding cured dental composites characterized by good mechanical properties, smooth surfaces, and very little wear on the dental antagonist (3:5-15).

Regarding claims 2-3: Jones *et al.* teaches a filler for dental composite materials comprising a polymerizable organic binder and a shaped filler in a quantity of 5-35 wt% {75-80 wt% total} (¶ 65-68), wherein the filler particles are obtained by spray drying and have the shape of a doughnut {torus} [instant claims 3] with an average external diameter of about 0.2 μm to 20 μm {with a mean size of 5 μm} [instant claim 2], further comprising a silica sol {$SiO_2$ particles dispersed in polymerizable resin} (¶ 1-2, 9-10, 29, 58, 68).

Regarding claims 4 and 14: Jones *et al.* teaches a shaped filler {torus} in a quantity of 5-35 wt% {75-80 wt% total filler} (¶ 65-68), with examples containing 62 wt% of doughnut shaped particles [instant claims 4 and 14] (¶ 55-56, table 4).

Regarding claims 5-7: Jones *et al.* teaches the filler contains additional fragment shaped and/or spherical shaped inorganic filler particles [instant claim 5] (¶ 31, 25-26, 55), specifically fumed silica [instant claim 6] (¶ 68) or spherical silica obtained by a silica sol [instant claim 7] (¶ 65).

Regarding claims 9-10: Jones *et al.* teaches the binder includes ethylenically unsaturated monomers and oligomers {bis-GMA, TEGDMA} [instant claim 9] (¶ 66, 68), curable chemically and/or photochemically [instant claim 10] (¶ 66, 68).

Regarding claims 12-13: Jones *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1].

Jones *et al.* does not teach an internal diameter of the torus-shaped filler of 0.2-20 μm [instant claim 12] or 0.2-20 μm [instant claim 13]. However, the Office takes Official Notice that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) [MPEP 2144.05]. At the time of invention a person of ordinary skill in the art would have found it obvious to have optimized the internal diameter, as taught by Jones *et al.*, as commonly practiced in the art, and would have been motivated to do so since the capability of the ceramic filler to mechanically lock into the resin matrix of the composition is influenced by the shape of the filler.

Regarding claims 15-16: Jones *et al.* teaches the filler particles comprise silicon dioxide and/or heavy metal oxides [instant claim 15] (¶ 31-48), specifically zirconium oxide, barium oxide, and strontium oxide [instant claim 16] (¶31-48, 66, 68).

Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jones *et al.* (US 2002/0193463); or Jones *et al.* (US 2002/0193463) in view of Heindl *et al.* (US 5,852,096).

Regarding claim 18: Jones *et al.* teaches a filler for dental composite materials (¶ 1-2, 9-10) comprising a polymerizable organic binder and a filler in a quantity of 5-35 weight%, wherein the filler particles are obtained by spray drying and have the shape of a doughnut {torus} with an average external diameter of about 5 μm and 15 μm (29, 58, 65-68); the filler particles undergo a heat treatment process at a temperature of about 600 °C {for about 24 h},

which completes the formation of holes within the discs and allows the smooth ovoid or round doughnut shaped particles to provide a lower residual stress within the matrix resin following polymerization (¶ 59). Jones *et al.* teaches the doughnut {torus} shaped filler particles are silanized (¶ 64).

Jones *et al.* does not teach post-curing the particles at a temperature of 800 – 1200 °C. However, the Office takes Official Notice that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) [MPEP 2144.05]. At the time of invention a person of ordinary skill in the art would have found it obvious to have optimized the furnace temperature, as taught by Jones *et al.*, as commonly practiced in the art, and would have been motivated to do so since the conversion of silica gel into silica glass, as well as the formation of holes in the discs, is influenced by the temperature of the furnace, which allows the smooth ovoid or round doughnut shaped particles to provide a lower residual stress within the matrix resin following polymerization (¶ 59).

Alternatively, Jones *et al.* does not teach post-curing the particles at a temperature of 800 – 1200 °C. However, Heindl *et al.* teaches silicon dioxide based filler for dental materials (1:5-10) wherein the filler is fired at 500 to 1000 °C after drying in order to reduce the percentage of silanol groups on the surface (3:5-15). Jones *et al.* and Heindl *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of silicon dioxide based filler for dental materials. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined firing at a temperature of 500 to 1000 °C after drying, as taught by Heindl *et al.* in the invention of Jones *et al.*, and would have been motivated

to do so since Heindl *et al.* suggests that the firing provides a reduced percentage of silanol groups on the surface of the filler, yielding cured dental composites characterized by good mechanical properties, smooth surfaces, and very little wear on the dental antagonist (3:5-15).

Jones *et al.* does not specifically teach a method of filling cavities in teeth with the material. However, at the time of invention a person of ordinary skill in the art would have found it obvious to have filled cavities in teeth based on the invention of Jones *et al.*, and would have been motivated to do so since Jones *et al.* suggests that the composition is useful as a dental filling material (¶ 1, 27, 68).

***Response to Arguments***

Applicant's arguments filed 10/12/09 have been fully considered but they are not persuasive. The rejection of claims 1-7 and 9-18 based upon Jones *et al.* (US 2002/0193463) is maintained for reason of record and following response.

Jones *et al.* (US '463) teaches a filler for dental composite materials (¶ 1-2, 9-10) comprising a polymerizable organic binder and a filler in a quantity of 5-35 weight% (¶ 65-68), wherein the filler particles are obtained by spray drying and have the shape of a doughnut {torus} with an average external diameter of about 0.2 μm to 20 μm {with a mean size of 5 μm} (¶29, 58); the filler particles undergo a heat treatment process at a temperature of about 600 °C {for about 24 h}, which completes the formation of holes within the discs and allows the smooth ovoid or round doughnut shaped particles to provide a lower residual stress within the matrix resin following polymerization (¶ 59). Jones *et al.* (US '463) specifically discloses the doughnut shaped particles have smooth surfaces (¶ 59). Furthermore, Figures 1-4 appear to show the smooth surfaces of the doughnut shaped particles (¶ 10-13). As a result, one having skill in the

art would realize heating the ceramic particle at a temperature of about 600 °C, or higher {800 to 1000 °C}, would complete the conversion of silica gel into silica glass, and also complete the formation of the holes in the discs.

Jones *et al.* (US '463) discloses the doughnut shaped particles have smooth surfaces (¶ 59), as Figures 1-4 appear to show the smooth surfaces of the doughnut shaped particles (¶ 10-13). The examiner interprets completes the formation of holes in the discs (¶ 59) as the formation of the torus {doughnut shaped} particle, having a smooth surface (¶ 10-13; Fig. 1-4).

In response to applicant's argument that post-curing at 800 to 1000 °C leads to particles with non-porous surfaces, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding post-curing at 800 to 1000 °C leads to particles with non-porous surfaces, and a treatment temperature around 600 °C leads to porous surfaces {Applicants' remarks (pg. 8, ln. 11 pg. 9, ln. 9)}, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) [See MPEP 716.01(c)]. It is unclear to the examiner where the data for such a comparison is supported from the specification, as pg. 11, ln. 24 - pg. 12, ln. 2 indicates post-curing of the fillers was carried out at 400-1200 °C, preferably at 600-900 °C; and post-curing at higher temperatures (800-900 °C) leads to filler agglomerates (Fig. 3) which, however, can again be deagglomerated by adding mechanical energy, such as for example ultrasound, and by obtaining the annular structure. Arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*,

100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) [See MPEP 2145]. A showing of unexpected results must be based on evidence, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) [See MPEP 2145].

Evidence {data} would need to be provided for a showing of unexpected results over the prior art of record. In an attempt to show unexpected results for post-curing at 800 to 1000 °C and the effect on the resulting particles, evidence {data} would need to be provided for a showing of unexpected results over the prior art of record. To establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960) [see MPEP 716.02(d)]. See also *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972).

The rejection of claims 1-7 and 9-18 based upon Jones *et al.* (US 2002/0193463) and Heindl *et al.* (US 5,852,096) is maintained for reason of record and following response.

Applicants' arguments regarding Jones *et al.* (US '463) have been sufficiently addressed above. Heindl *et al.* (US '096) was relied on for disclosing silicon dioxide based filler for dental materials (1:5-10) wherein the filler {silicon dioxide} is fired at 500 to 1000 °C after drying in order to reduce the percentage of silanol groups on the surface (3:5-15). The reference must be considered for all that it discloses and must not be limited to preferred embodiments [see MPEP 2123]. One having skill in the art would realize silicon dioxide is fired at 500 to 1000 °C after drying in order to reduce the percentage of silanol groups on the surface, as this is suggested

from prior art pertaining to dental composites comprising silicon dioxide which is subsequently surface treated with a silane (3:5-15).

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### *Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
24-February-10

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796